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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,216	12/02/2003	Timothy C. Nichols	421/29/2/2	4262

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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	**PAPER NUMBER**
1647	

MAIL DATE	DELIVERY MODE
09/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,216	NICHOLS ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *13-44 and 55-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 45-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 13-44 and 55-78 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/06.

Claims 1-12 and 45-54 are under consideration by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 45-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

This rejection is maintained for reasons of record.

Applicant argues that the presence of the calcium channel on the surface of a platelet or at least present in a cell membrane is not required for operability of the method.

Applicant's arguments are not persuasive. The cell free system described on page 71 either requires a lipid bi-layer (cell membrane) or will only measure binding to the calcium channel. A lipid bi-layer is not required by the claims. Measuring biological activities such as calcium transport or phosphatidylserine exposure require more than just the calcium channel

polypeptide alone. These are processes that take place in the cell membrane. They require other cellular components. The claims are not limited to binding nor do they appear to intend a binding assay. Applicant has not explained how binding alone will provide a determination of the ability of the candidate substance to modulate phosphatidylserine exposure on the surface of the platelet. Applicant has not explained how determining another unspecified biological activity will provide a determination of the ability of the candidate substance to modulate phosphatidylserine exposure on the surface of a platelet. There is no disclosure or guidance on such methods in the specification. The steps set forth in the claims will not achieve the recited goal of the preamble.

With respect to the amendments to claims 5-6, the specification does not disclose a platelet in cell culture or a recombinant platelet and there is no guidance on other cells or cell lines predictive of phosphatidylserine exposure in platelets. As such, it is unknown what method is intended by these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 45-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The steps in claim 1 are inconsistent with the goal of the preamble, particularly as applicant argues that the test sample of (a) does not require a platelet even though the preamble and part (c) refer to platelets. This claim is confusing. See enablement rejection above.

Claim 4 has been interpreted to mean that the nucleic acid molecule encoding the channel has been expressed to produce the polypeptide recited in claim 1 part (a). However, it could be interpreted that the nucleic acid molecule and calcium channel polypeptide are discrete components of the test sample. Claim 48 is similarly confusing.

Claim 7 as amended is confusing as it does not require that the calcium channel be present on the surface of the platelet or in any way associated with the platelet. That is, the calcium channel polypeptide and platelet could be discrete components of the test sample.

It is maintained that claims 3 and 47 are confusing because the limitations set forth therein do not further modify the methods of claims 1 and 45. Applicant's arguments are noted but the response does not explain what aspect of the method of screening is further limited by these claims or why this additional step is considered a screening step. The arguments appear to focus on why one would want to clone the gene or what other methods that would involve cloning the gene (e.g. a method of producing the candidate polypeptide). This is not the basis for this rejection. It is noted that applicant's arguments are considered to limit the scope of claims 3 and 47 to screening candidate polypeptides and no other candidate substances.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-7, 11-12, 45-46, and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunzelmann-Marche et al. in view of Malouf et al. (US 2002/0165353 A1).

This rejection is maintained for reasons of record.

Applicant argues they are entitled to the filing date of parent application 10/029,413, namely 20 December 2001. This is not agreed with. This parent application does not disclose the presently claimed methods. At least for example, the parent application does not disclose modulating phosphatidylserine exposure on the surface of a platelet. (See claims 1-12 and 51-54.) Applicant argues that claim 45 of the instant application is the same as original claim 38 of parent application 10/029,413. This is incorrect as part (a) of claim 38 reads "establishing a test sample comprising a **nucleic acid molecule**" (emphasis added) whereas instant claim 45 is directed to a polypeptide. However, even if the claims used identical language, the claims are read in light of the specification with respect to what they intend. The parent application has no disclosure or examples of phosphatidylserine exposure as an intended activity for this channel whereas much of the disclosure and examples is with respect to these concepts. When read in light of the specification, the instant claims fairly embrace concepts not contemplated by the

parent application. Modulating phosphatidylserine exposure is clearly contemplated and embraced by the instant claims whereas it was not contemplated by the parent application. As such, applicant is entitled to only the instant filing date of 2 December 2003. Malouf et al. (US 2002/0165353) was published 7 November 2002 and is a valid prior art reference.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marianne P. Allen

Marianne P. Allen
Primary Examiner
Art Unit 1647

9/18/07

mpa